

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **15.02.2005**

Applicant's or agent's file reference

**ONF-5145PCT**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/012768**

International filing date (day/month/year)

**27.08.2004**

Priority date (day/month/year)

**29.08.2003**

International Patent Classification (IPC) or both national classification and IPC

**C07C229/14, 229/22, 229/36, 233/47, 255/16, 255/41, 271/22, C07D205/04, 211/04, 217/04, C07D405/06, A61K31/11, 31/135, 31/197, 31/198, 31/222,**

Applicant

**ONO PHARMACEUTICAL CO., LTD.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/012768

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/012768

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 40-41

because:

☒ the said international application, or the said claims Nos. 40-41  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

These claims pertain to methods for treatment of the human body by therapy. Thus, this International Preliminary Examining Authority is not required to carry out international preliminary examination on this subject matter under the provisions of PCT Article 34(4)(a)(i) and PCT Rule 67.1(iv).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 40-41

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/012768

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	22, 24-26, 29-30, 36, 38	YES
	Claims	1-21, 23, 27-28, 31-35, 37, 39, 42-43	NO
Inventive step (IS)	Claims	22, 24-26, 29-30, 36, 38	YES
	Claims	1-21, 23, 27-28, 31-35, 37, 39, 42-43	NO
Industrial applicability (IA)	Claims	1-39, 42-43	YES
	Claims		NO
<b>2. Citations and explanations:</b>			
<p>Document 1: WO 03/061567 A2 (Merck &amp; Co., Inc.), 31 July 2003 &amp; EP 1469863 A2 &amp; US 2004/058894 A1</p> <p>Document 2: WO 03/062248 A2 (Merck &amp; Co., Inc.), 31 July 2003 (Family: none)</p> <p>Document 3: WO 03/062252 A1 (Merck &amp; Co., Inc.), 31 July 2003 &amp; EP 1470137 A1</p> <p>Document 4: WO 02/092068 A1 (Ono Pharmaceutical Co., Ltd.), 21 November 2002 &amp; EP 1391199 A1 &amp; US 2004/224941 A1</p> <p>Document 5: WO 02/18377 A1 (Pharmacia Corporation), 7 March 2002 &amp; EP 1320530 A1 &amp; JP 2004-521079 A &amp; US 2002/072518 A1</p> <p>Document 6: WO 96/13497 A1 (Terumo Corporation), 9 May 1996 &amp; EP 790247 A1 &amp; JP 2819436 B &amp; US 5789595 A</p>			
<p>The inventions set forth in claims 1 to 3, 6, 7 and 11 to 21 are disclosed in document 1 cited in the international search report, and therefore lack novelty and do not involve an inventive step.</p> <p>The inventions set forth in claims 1 to 3, 6, 7 and 11 to 21 are disclosed in document 2 cited in the international search report, and therefore lack novelty</p>			

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/012768

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

and do not involve an inventive step.

The inventions set forth in claims 1 to 3, 5 to 8 and 11 to 21 are disclosed in document 3 cited in the international search report, and therefore lack novelty and do not involve an inventive step.

The inventions set forth in claims 1, 27, 28, 31 to 35, 37, 39, 42 and 43 are disclosed in document 4 cited in the international search report, and therefore lack novelty and do not involve an inventive step.

The inventions set forth in claims 1 to 4, 8 to 21, 23, 27 and 37 are disclosed in document 5 cited in the international search report, and therefore lack novelty and do not involve an inventive step.

The inventions set forth in claims 1 to 4, 8 to 21, 23, 27 and 37 are disclosed in document 6 cited in the international search report, and therefore lack novelty and do not involve an inventive step.

The inventions set forth in claims 22, 24-26, 29-30, 36 and 38 are not disclosed in any of the documents cited in the international search report or any other documents acknowledged to be relevant to these inventions, and would not be obvious to a person skilled in the art.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/JP2004/012768

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Although the claims cover all cyclic carboxylic acids including benzoic acid, only those having a nitrogen atom on the chain Y, described in the description, are disclosed within the meaning of PCT Article 5, hence support within the meaning of PCT Article 6 is lacking.

Therefore, the search has been conducted on the scope supported by and disclosed in the description, namely, those having a nitrogen atom on the chain Y, concretely described in the description.